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MAVIG

FDA/CDRH/ODE/P510 NOV 21 2006

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MAVIG GmbH · Postfach 820362 · 80803 München · Germany

K-40

Section 5

510(k) SUMMARY

Type:	Traditional
510k Submitter:	**MAVIG GmbH** Stahlgruberring 5 81829 Munich Bavaria Germany phone (+49 89) 420 96 -0 fax (+49 89) 420 96 -200 e-mail info@mavig.com
Contact Person:	Christian Stoian CEO Christian.stoian@mavig.com phone (+49 89) 420 96 -233
Preparation Date:	4th August 2006
Trade Name:	M3
Common Name:	Surgical Lamp
Classification Name:	Light, Surgical, Ceiling Mounted
Class:	Class II
Recommended Classification Regulation:	878.4580
Product Code:	FSY
Panel:	General & Plastic Surgery

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Device Description:

The M3 Surgical Light is suitable for all types of of surgical procedures. With its advanced technology of R96 light technology, the M3 realizes a high illumination intensity with a lower heat radiation. The light incorporates easy-to-move swivel arms, three halogen bulbs, and an easy-to-exchange lamp cartridge. Also an optional Video camera or video preparation is available. The lamp can be combined with other lights provided by MAVIG.

Indications for Use of the Device:

The surgical light M3 is intended to illuminate locally the operating site on the patient's body with a high intensity, shadow-free, "cold" light.

Intended Use of the Device:

The M3 lighting system is for illuminating an examination and surgical site on the patient in the clinic and doctor's office.

Predicate Device

Chromophare X65, K024132.

Substantial Equivalence:

The M3 is substantially equivalent to the surgical light CHROMOPHARE X 65. Any difference that exists between the CHROMOPHARE X 65 and the M3 has no negative effect on safety or effectiveness and actually enhances the usefulness in the choosen application.

Main Difference to Predicate:

	M3	Chromophare X65
Reflector System	Multi-reflector system with 3 glass reflectors, specially coated heat protection filter	One-reflector system with polygon reflector
Light Source	3 halogen bulbs 24V/50W	2 discharge lamps with automatic switch-over function
Duo-Focus Technology	Allows a bigger setting range of the light field size (suitable for very small and deep wound areas)	Not available

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAVIG GmbH
% Underwriters Laboratories, Inc.
Mr. Jeffrey D. Rongero
Senior Project Engineer
12 Laboratory Drive
Research Triangle Park, North Carolina 27709

NOV 2 1 2006

Re: K063333
Trade/Device Name: M3
Regulation Number: 21 CFR 878.4580
Regulation Name: Surgical lamp
Regulatory Class: II
Product Code: FSY
Dated: October 20, 2006
Received: November 6, 2006

Dear Mr. Rongero:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4

Indications for Use

510(k) Number (if known): K063333

Device Name: **M3**

Indications for Use: The surgical light M3 is intended to illuminate locally the operating site on the patient's body with a high intensity, shadow-free, "cold" light.

Prescription Use **X**
(Part 21 CFR 801 Subpart D)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhoan

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K063333

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